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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,464

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EXAMINER

SNYDER, STUART

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/583,464	Applicant(s) ARUMUGHAM ET AL.	
	Examiner STUART W. SNYDER	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 384,386,387,392,394-396 and 402 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 384,386,387,392,394-396 and 402 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/30/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

1. Claims 383, 386-387, 392, 394-396 and 402 are pending and examined herein. Amendment of claims 384, 386, 392, and 394; cancellation of claims 370-383, 385, 388-391, 393, and 397-401; and addition of new claim 402 in Applicants' filing of 6/30/2010.

Claim Objections

2. Objection to claims 384-391 is **withdrawn** in view of amendment of claim 384.

Claim Rejections - 35 USC § 112

3. Rejection of claims 388-396 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in view of claim 392.

Claim Rejections - 35 USC § 102

4. Rejection of claims 384, 387, 392 under 35 U.S.C. 102(b) as being anticipated by Conley, *et al.* is **withdrawn** in view of Applicants' arguments filed 6/30/2010. Rejection of claims 385, 388-389, 391, 393, and 395 under 35 U.S.C. 102(b) as being anticipated by Conley, *et al.* is moot and **withdrawn** in view of cancellation of the claims.
5. Rejection of claims 392 and 394 under 35 U.S.C. 102(b) as being anticipated by Mariotti, *et al.* is **withdrawn** in view of Applicants' arguments filed 6/30/2010. Rejection of claims 393 and 395 under 35 U.S.C. 102(b) as being anticipated by Mariotti, *et al.* is moot and **withdrawn** in view of cancellation of the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Rejection of claims 392 and 396 rejected under 35 U.S.C. 103(a) as being unpatentable over Conley, *et al.* is **withdrawn** in view of Applicants' arguments filed 6/30/2010.
7. Rejection of claims 384, 386, 392 and 394 under 35 U.S.C. 103(a) as being unpatentable over Conley, *et al.* in view of Mariotti, *et al.* is **withdrawn** in view of Applicants' arguments filed 6/30/2010. Rejection of claims 385, 388-390, and 393 under 35 U.S.C. 103(a) as being unpatentable over Conley, *et al.* in view of Mariotti, *et al.* is moot and **withdrawn** in view of cancellation of the claims.
8. Rejection of claims 385 and 388-390 under 35 U.S.C. 103(a) as being unpatentable over Mariotti, *et al.* in view of Conley, *et al.* is moot and **withdrawn** in view of cancellation of the claims.
9. Claims 384 and 386-387 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mariotti, *et al.* in view of Conley, *et al.* The claims are drawn to compositions comprising, inter alia, a conjugate comprising a CRM₁₉₇ and an immunogenic peptide wherein unreacted crosslinking agents on CRM₁₉₇ are capped. The relevance of Mariotti, *et al.* in view of Conley, *et al.* was discussed in the previous Office Action and is essentially that heterologous, immunogenic

peptides were conjugated to CRM₁₉₇ (Mariotti, *et al.*) whereas capping of unreacted crosslinking agents are capped on conjugates of an OMPC (Conley, *et al.*). Applicants argue for the non-obviousness of combination of the two methods by arguing that neither method discusses the necessity to maintain immunogenicity by capping unreacted crosslinking agents. However, Conley, *et al.* does not need to make such an argument in view of the fact that 3 of the 5 peptidyl conjugates presented in Figure 3 maintained significant immunogenicity. Furthermore, under ordinary conditions, a skilled artisan would have recognized that unreacted crosslinking agents have the potential to crosslink with undesired elements within solutions containing such; the simplest such unwanted reaction would be the multimerization of conjugates themselves or other proteins in immune solutions that may serve as adjuvants or stabilizers. Thus, Applicants' arguments regarding the non-obviousness of combining Mariotti, *et al.* and Conley, *et al.* are irrelevant and unconvincing.

10. Claims 392 and 394-396 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mariotti, *et al.* in view of Conley, *et al.* The claims are drawn to compositions comprising peptide immunogens on protein carriers add the following limitations: The compositions further comprise excipients, diluents and/or adjuvants (claim 392); the carrier is CRM₁₉₇ (claim 394); the peptide immunogen is selected from certain recited classes of proteins especially including viral proteins (claim 395); and the adjuvants are selected from a list of several especially including alum. Conley, *et al.* teaches the use of adjuvants,

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especially alum and aluminum phosphate (see line 35, p. 19) and HCV peptides conjugated to OMPC whereas Mariotti, *et al.* teaches that the carrier is CRM₁₉₇.

Thus, each and every limitation of claims 392 and 394-396 is taught by the combination of Conley, *et al.* and Mariotti, *et al.*

A skilled artisan would find it obvious to add adjuvants, especially alum, and attach viral peptides to the carrier CRM₁₉₇. The skilled artisan would be motivated to increase the immunogenicity of the viral peptides by using alum and multiplex the immunogens by attaching to a carrier; furthermore, alum is one of the few FDA approved adjuvants. CRM₁₉₇ has successfully been used a carrier as taught by Mariotti, *et al.* as has the use of alum as an adjuvant. Thus, the invention of claims 392 and 394-396 is *prima facie* obvious over the combination of Mariotti, *et al.* and Conley, *et al.*

11. Claim 402 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mariotti, *et al.* and Conley, *et al.* as applied to claim 384 above in further view of Joyce, *et al.* (Isolation, structural characterization, and immunological evaluation of a high-molecular-weight exopolysaccharide from *Staphylococcus aureus*. Carbohydrate Research. 2003; 338:903–922) (see p. 921, first column). The claim is drawn to compositions comprising peptide immunogens on protein carriers in which unreacted linkers are capped with N-acetylcysteamine (NAC), among other capping reagents. N-acetylcysteamine capping is taught by Joyce, *et al.* when making a multiplexed immunogen. Thus, each and every limitation of

the claim is taught by the combination of Mariotti, *et al.*, Conley, *et al.*, and Joyce, *et al.*

A skilled artisan would have found it obvious to use NAC as a capping reagent. The skilled artisan would have been motivated to remove unreacted and potentially chemically active reagents uncapped. The skilled artisan would have a reasonable expectation of success given the reagent is well suited to react with nucleophilic crosslinkers as were used by Joyce, *et al.* Thus, the invention of claim 402 is *prima facie* obvious over the combination of Mariotti, *et al.*, Conley, *et al.*, and Joyce, *et al.*

Double Patenting

12. Claims 384, 386-387, 392, 394-396 and 402 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 398 of copending Application No. 10/583,503. Although the conflicting claims are not identical, they are not patentably distinct from each other because they recite the same limitations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

13. No claims are allowed.
14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to STUART W. SNYDER whose telephone number is (571)272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ZACHARIAH LUCAS can be reached on (571)272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/
Primary Examiner, Art Unit 1648

Stuart W Snyder
Examiner
Art Unit 1648

SWS